IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the patent of:	)
	)
Don A. Perry and H. Earl Wright	)
	)
Title: Touch Enhancing Pad	)
	)
U.S. Pat. No. Re. 34,353	)
	)
Issued August 24, 1993	)

AMENDED APPLICATION FOR EXTENSION OF PATENT TERM

Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Dear Sir:

Inventive Products, Inc. ("IPI") applies for an extension of the term of U.S. Pat. No. Re. 34,353 pursuant to 35 U.S.C. § 156 and 37 C.F.R. §§ 1.701 et seq. This amended application is being submitted in response to the Notice of Deficiencies dated October 31, 1996.

THE APPROVED PRODUCT

The approved product is the SENSOR PAD® touch enhancing pad (the "Sensor Pad"). The Sensor Pad is a thin polyurethane bladder containing a small quantity of liquid silicone lubricant. The Sensor Pad enhances the sense of touch when placed between the fingertips and the object to be examined. The bottom layer of the enclosure (the one in contact with the object being examined) remains stationary while the top layer (the one in contact with the fingertips) moves with the fingertips. The Sensor Pad has many uses, but the primary emphasis of marketing has been for use as an aid in breast self-examination.

THE FEDERAL STATUTE

The Federal statute under which the regulatory review of the Sensor Pad occurred is the Food, Drug and Cosmetic Act, 21 U.S.C. § § 301 et seq. (the "Act"). In particular, regulatory review of the Sensor Pad occurred under the Medical Device Amendments to the Act, Pub. L. No. 94-295 (1976).

THE DATE ON WHICH THE PRODUCT RECEIVED PERMISSION FOR COMMERCIAL MARKETING

The Sensor Pad was approved for sale as an aid to breast self-examination, subject to the general control provisions of the Act, by the Food and Drug Administration ("FDA") on December 22, 1995.

STATEMENT RE THE SIXTY DAY PERIOD

The original application was submitted within the sixty day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last day on which the original application could have been submitted was February 20, 1996.

THE PATENT

The patent is Perry et al., U.S. Pat. No. Re. 34,353, issued August 24, 1993, entitled *Touch Enhancing Pad*. Its expiration date is April 24, 2005. The patent is a reissue of Perry et al., U.S. Pat. No. 4,657,021, issued April 14, 1987. A photocopy of this patent was enclosed with the original application. Also enclosed with the original application were photocopies of a maintenance fee statement dated December 13, 1990; a maintenance fee statement dated May 26, 1994; and a certificate of correction dated August 30, 1994.

STATEMENT RE THE PATENT CLAIMS

The Patent claims the approved product. In particular, claim 12 of the Patent reads on the Sensor Pad as shown in the following demonstration.

The preamble of claim 12 recites "An apparatus which enhances the sense of touch when placed between the fingertips of the user and the object being touched." The Sensor Pad meets this recitation.

The transition of claim 12 is "the apparatus comprising." The body of the claim recites two elements, an enclosure and a liquid lubricant. Each of these elements is discussed in turn:

The enclosure is described as "a sealed enclosure of a plurality of pieces of a pliable, elastic material having a wall thickness of about 0.005 to 0.050 inches, a modulus at 300 percent elongation of less than about 1,500 psi, a tensile strength of greater than about 3,000 psi, and an ultimate elongation of greater than about 400 percent...." The enclosure of the Sensor Pad is made of two pieces of DUREFLEX™ PT6300 polyurethane film having a wall thickness of about 0.006 inches. The polyurethane film has a modulus at 300 percent elongation of about 1,650 psi, a tensile strength of about 8,000 psi, and an ultimate elongation of about 650 percent.

The lubricant is described as "a liquid lubricant inside the enclosure which has sufficient lubricity to reduce the coefficient of kinetic friction between the interior wall of the enclosure by at least about 60 percent so that the bottom wall of the pad remains stationary over the object being touched while the top wall moves freely with the fingertips, a sufficiently-high resistance to mass transfer through the enclosure so that the amount of lubricant inside the enclosure remains substantially constant over time, substantial inertness towards the enclosure, and which is present in an amount sufficient to fully coat the interior of the enclosure...." The Sensor Pad contains about 20 cc of ORGANOSILICONE L-45 polydimethylsiloxane fluid (a liquid silicone lubricant) that meets all the above elements.

STATEMENT RE DETERMINATION OF THE REGULATORY REVIEW PERIOD

The Sensor Pad was not a significant risk device, so no application was necessary or appropriate for an investigational device exemption (IDE). The Applicant began the first clinical investigation of involving the Sensor Pad on January 17, 1986. The investigation was a study entitled "Lump Detection In Females Using The Preferred Hand With And Without The Sensor Pad" conducted by Donna Rene Verry, Ph.D., a professor at Millikin University, Decatur, Illinois.

The application for premarket approval (PMA) under section 515 of the Act, which included the results of the clinical investigation by Dr. Verry, was received by the FDA on September 27, 1989. The PMA Number was P890052.

The Sensor Pad was cleared for sale, with an indication as an aid to breast self-examination, on December 22, 1995.

BRIEF DESCRIPTION OF THE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD

The Applicant originally mailed an application under Section 510(k) of the Act on or about April 15, 1985. The application was received by the FDA on April 29, 1985 and assigned Document Control Number K851700. The Applicant was waiting for action on this 510(k) application when the first clinical investigation was begun on January 17, 1986.

On or about June 18, 1986, the Applicant received a letter from the FDA informing it that the Sensor Pad was not substantially equivalent to an existing approved product and that an application for premarket approval (PMA) needed to be filed.

Representatives of the Applicant held numerous discussions with the FDA until a PMA application was filed on September 27, 1989. The application was assigned Document Control Number P890052. On December 11, 1989, the FDA notified the Applicant that the PMA application was incomplete.

Representatives of the Applicant continued to hold numerous discussions with the FDA. A second 510(k) application was filed on January 14, 1993. The application was assigned Document Control Number K930308.

On June 18, 1993, the Applicant received a letter from the FDA informing it that the Sensor Pad was not substantially equivalent to an existing approved product.

The Applicant filed a third 510(k) application on November 7, 1995. The application was assigned Document Control Number K955094. A clearance letter was issued on November 9, 1995.

A fourth 510(k) application was filed by the Applicant on November 15, 1995. The application was assigned Document Control Number K955249. A clearance letter was issued on December 22, 1995.

STATEMENT RE OPINION OF ELIGIBILITY

The Applicant is of the opinion that the patent is eligible for an extension of two years and 166 days. This term is the period beginning on the date the original patent issued (April 14, 1987) and ending on the date the application for product approval under section 515 of the Act was received by the FDA (September 27, 1989).

STATEMENT RE DUTY OF DISCLOSURE

The Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

INQUIRIES AND CORRESPONDENCE

Please direct all inquiries and correspondence relating to this application for patent term extension to Philip L. Bateman, P.O. Box 1105, Decatur, Illinois 62525 and direct all telephone calls to Mr. Bateman at (217) 429-6400. Mr. Bateman is a registered patent attorney, Registration No. 30,127.

DECLARATION

I, Grant A. Wright, declare that I am the president of the Applicant corporation and am authorized to obligate the corporation.

I have reviewed and understand the contents of the Application.

I believe the Patent is subject to extension pursuant to 37 C.F.R. § 1.710.

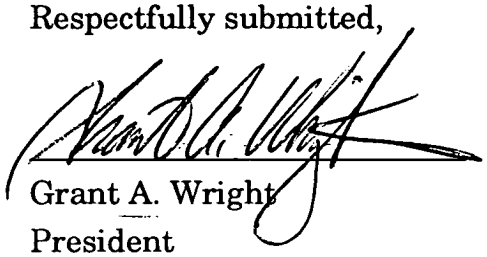
I believe the extension of the length claimed is justified under 35 U.S.C. § 156 and the applicable regulations.

I believe the Patent meets the conditions for extension of the term of a patent is as set forth in 37 C.F.R. § 1.720.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge

that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the Patent.

Respectfully submitted,



Grant A. Wright
President
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CERTIFICATE OF MAILING

Philip L. Bateman certifies that duplicate copies of this Amended Application For Extension Of Patent Term are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Box Patent Extension, Washington, D. C. 20231 on November 27, 1996.

Philip L. Bateman

Philip L. Bateman